

**Section XII: 510(k) Summary of Safety and Effectiveness**

FEB - 6 2004

**SAFE MEDICAL DEVICES ACT OF 1990**  
510(k) Summary

K033756  
page 1 of 1

**NAME OF FIRM:** I.T.S. Implantat-Technologie-Systeme GmbH.  
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Lassnitzhoehe A - 8301  
AUSTRIA

**510(k) FIRM CONTACT:** Al Lippincott  
Engineering Consulting Services, Inc.  
3150 E. 200<sup>th</sup> St.  
Prior Lake, MN 55372

**TRADE NAME:** Volar Radius Plate with Angular Stability

**COMMON NAME:** Fracture Fixation Plating system for fracture fixation of the end of long bones

**CLASSIFICATION:** Single/multiple component metallic bone fixation appliances and accessories (see 21 CFR, Sec. 888.3030).

**DEVICE PRODUCT CODE:** HRS

**SUBSTANTIALLY EQUIVALENT DEVICES:** Avanta SCS/V Distal Radius Plate - Volar  
Hand Innovations DVR Plate  
Synthes Locking Distal Radius System 2.4

**DEVICE DESCRIPTION:** The I.T.S. Volar Radius Plate with Angular Stability provides various width 4 and 6 hole standard plates, various width 8, 10, and 12 hole long plates, various length stabilization screws, and various length cortical fixation screws. The volar radius plates are made from CP Titanium according to ASTM F 67-00 and the screws are made from 6-4 Alloyed Titanium according to ASTM F 136-98.

**INTENDED USE:** The I.T.S. Volar Radius Plate is used to stabilize distal radius fractures in the wrist with an accurate retention of articular fracture elements.

**BASIS OF SUBSTANTIAL EQUIVALENCY:** The I.T.S. Volar Radius Plate is substantially equivalent to the Avanta, Hand Innovations, and Synthes fracture plating systems

**SUMMARY OF SAFETY AND EFFECTIVENESS:** The I.T.S. Volar Radius Plate system is shown to be safe and effective for use in fracture fixation of the distal radius in the wrist.



FEB - 6 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

I.T.S. Implantat-Technologie-Systeme GMBH  
Al Lippincott  
c/o Engineering Consulting Services, Inc.  
3150 East 200<sup>th</sup> Street  
Prior Lake, Minnesota 55372

Re: K033756

Trade/Device Name: Volar Radius Plate with Angular Stability  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Code: HRS  
Dated: November 24, 2003  
Received: December 1, 2003

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

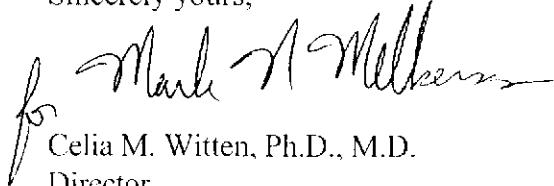
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Mr. Al Lippincott

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized initial "C" and a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



# Spectromed

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FN 163966 b, DVR 0934704

510(k) NUMBER: K033756

DEVICE NAME: Volar Radius Plate

INDICATIONS FOR USE:

The I.T.S. Volar Radius Plate with Angular Stability is a titanium implant fracture fixation system for distal radius fractures of the wrist.

Indications for Use include comminuted extra and intra-articular distal radius fractures, failed original fracture fixation, osteotomy and repair of a distal radius malunion, and comminuted volar shearing fractures

The I.T.S. Volar Radius Plate system provides immediate stability, rapid recovery, and prompt wrist functionality.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter-Use  
(Optional Format)

*for Mark H. Miller*

Device Number: K033756

